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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,344	11/21/2005	Dirk Mertin	LeA 36165	9502

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BAYER HEALTHCARE LLC
P.O.BOX 390
SHAWNEE MISSION, KS 66201

EXAMINER	
DICKINSON, PAUL W	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,344	MERTIN ET AL.	
	Examiner	Art Unit	
	PAUL DICKINSON	4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/28/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-10 are pending and currently under consideration.

Claim Objections

Claim 2 is objected to because of the following informalities: The phrase "characterized in that as pseudoplastic gel former it comprises polyacrylic acid..." is grammatically incorrect. Appropriate correction is required.

Claim Rejections - 35 USC § 101/112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 provides for the use of pharmaceutical preparations, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass

Similarly, Claim 10 provides for the use of pseudoplastic gel formers, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass.

A claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is

not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Furthermore, a claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

A single claim which recites both a product and method steps of using that product is indefinite under 35 USC 112, second paragraph. See Ex parte Lyell, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990). Such claims should also be rejected under 35 USC 101 on the theory that the claim is directed to neither a "process" nor a "machine", but rather embraces or overlaps two different statutory categories of invention set forth under that statute, which is drafted so as to set forth the statutory classes of invention in the alternative only. Id. At 1551.

Claim 9 recites both a product (pharmaceutical preparations) and a process (oral administration). Similarly, Claim 10 recites both a product (pseudoplastic gel formers) and a process (improving the properties of liquid suspensions). Claims 9 and 10 are thus rejected as follows on the theory that the claim is directed to neither a "process" nor a "product" exclusively:

1) Claims 9 and 10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

2) Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7, 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5152986 (hereafter '986). '986 discloses ion exchange resins which are loaded with quinolonecarboxylic acid derivatives, and their preparation (see entire document; abstract; col 1, ln 9-11). '986 discloses a formulation comprising enrofloxacin (a quinolone antibiotic) bound to Lewatit® SPC 108 H^+ (an acidic ion exchanger; see US 20070203369, ¶ 74) dispersed in a carrier medium comprising methylhydroxypropyl cellulose gel (a cellulose ether) (see Example 2; Formulation Examples). '986 does not explicitly state that there is water present in the formulation. There are no precautions to absolutely exclude moisture in the final formulation, however, and water is reasonably present in the carrier medium. There are many potential water sources, including incomplete drying of the enrofloxacin/resin complex, glycerol, benzyl alcohol, the flavoring, or the methylhydroxypropyl cellulose gel.

Instant Claim 9 is directed to the use of pharmaceutical preparations according to Claim 1 for oral administration. Instant Claim 10 is directed to the use of pseudoplastic gel formers for improving the properties of liquid suspensions. As stated in the section entitled Claim Rejections - 35 USC § 101/112, these claims are directed to non-statutory subject matter. For the purposes of comparing the instant claims to the prior art, the Examiner is interpreting one possible embodiment of Instant Claim 9 to encompass oral administration of the formulation of Claim 1. '986 teaches oral administration of the disclosed formulation to piglets, dogs and cats. The formulation disclosed by '986 therefore anticipates at least one possible embodiment Instant Claim 9. Furthermore, the Examiner is interpreting one possible embodiment of Instant Claim 10 to encompass a pseudoplastic gel former that, upon addition to a liquid suspension, alters at least one property of the liquid suspension. '986 teaches addition of methylhydroxypropyl cellulose gel (a pseudoplastic gel former) to a liquid suspension, altering at least one property, namely, the viscosity of the liquid. The formulation disclosed by '986 therefore anticipates at least one possible embodiment of Instant Claim 10.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5152986 (hereafter '986) in view of US 6323213 (hereafter '213). As stated above, '986 discloses ion exchange resins which are loaded with quinolonecarboxylic acid derivatives, and their preparation. '986 discloses a formulation comprising enrofloxacin bound to Lewatit® SPC 108 H^+ dispersed in a carrier medium comprising methylhydroxypropyl cellulose gel (a cellulose ether). '986 discloses the benefit of the disclosed formulation in providing improvement in taste and that the animal subjects who were administered the patent formulation accepted the material more readily than

other formulations (see abstract). '986 fails to disclose a preparation wherein the active substance bound to the ion exchanger is pradofloxacin.

'213 discloses that enrofloxacin is a known member of the class of antibiotics entitled quinolinecarboxylic acids and is widely used in veterinary medicine (see col 1, ln 15-20). '213 discloses the preparation and utility of pradofloxacin (see entire document; col 2, ln 35-41; Example 1). '213 discloses that pradofloxacin has a more potent antibacterial action compared with known representatives of the compound's structural type and are suitable for human and veterinary medicine.

One of ordinary skill in the art would be motivated to combine the disclosures of '986 and '213 to afford the instant invention, with a reasonable expectation of success. Specifically, one would be motivated to substitute enrofloxacin in the formulation disclosed by '986 for pradofloxacin. The motivation to make such a substitution stems from the structural similarities of pradofloxacin and enrofloxacin and the enhanced antibacterial action (extending even to humans) of pradofloxacin over enrofloxacin.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5152986 (hereafter '986) in view of US 6667058 (hereafter '058). As stated above, '986 discloses ion exchange resins which are loaded with quinolonecarboxylic acid derivatives, and their preparation. '986 discloses a formulation comprising enrofloxacin bound to Lewatit® SPC 108 H^+ (an acidic ion exchanger) dispersed in a carrier medium comprising methylhydroxypropyl cellulose gel (a cellulose ether). '986 discloses the benefit of the disclosed formulation in providing improvement in taste and that the

animal subjects who were administered the patent formulation accepted the material more readily than other formulations (see abstract). '986 fails to disclose a preparation wherein the active substance bound to the ion exchanger is flupirtine.

'058 discloses pharmaceutical dosage units containing flupirtine (see entire document). '058 discloses that flupirtine is a useful analgesic agent and that there is a need in the art to find improved flupirtine formulations (see col 1, ln 10-21). '058 discloses compositions of flupirtine prepared by binding flupirtine to acidic ion exchangers (see col 2, ln 51 to col 3, ln 15). A general procedure is provided outlining how to bind the drug to an acidic ion exchanger. '058 teaches the resulting flupirtine charged ion exchangers can be suspended in excipients such as thickening agents, flavoring substances, stabilizing substances and preservatives for administration.

One of ordinary skill in the art would be motivated to combine the disclosures of '986 and '058 to afford the instant invention, with a reasonable expectation of success. Specifically, in the search for improved analgesic formulations, one would be motivated to substitute enrofloxacin in the formulation disclosed by '986 for flupirtine. The motivation to do this stems from the fact that the animal subjects who were administered the formulation disclosed by '986 accepted the material more readily than other formulations, making the formulation disclosed by '058 a desirable formulation to explore. The motivation to substitute enrofloxacin for flupirtine stems from (1) the precedent of flupirtine in the art as an effective analgesic agent, and (2) the drug's affinity for acidic ion exchangers and the known procedure for binding flupirtine to acidic ion exchangers.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 8:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Dickinson
Examiner
AU 4173

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER